

# MEDICATION COVERAGE POLICY

## PHARMACY AND THERAPEUTICS ADVISORY COMMITTEE

<b>POLICY:</b>	Parasitic Disorders	<b>P&amp;T DATE:</b>	2/12/2019
<b>THERAPEUTIC CLASS:</b>	Infectious Disease	<b>REVIEW HISTORY:</b>	12/17, 12/16,
<b>LOB AFFECTED:</b>	Medi-Cal	<b>(MONTH/YEAR)</b>	5/15, 5/13

*This policy has been developed through review of medical literature, consideration of medical necessity, generally accepted medical practice standards, and approved by the HPSJ Pharmacy and Therapeutic Advisory Committee.*

## # OVERVIEW

**Table 1: Formulary Parasitic Agents: (Current as of 12/2018)**

Generic Name (Brand Name)	Strengths	Formulary Limits	Avg Cost per Month	Notes
<b>Topical Scabicide, Antiparasitic Pediculocide Agent</b>				
<b>LICE TREATMENT (Pediculocide):</b>				
Benzyl Alcohol (Ulesfia)	Ulesfia 5% Lotion	ST,PA	\$256.84	Reserved for treatment failure of Spinosad (Natroba) AND Malathion (Ovide) in the last 30 days
Benzy Benzoate	28% Lotion	NF	--	
Ivermectin (Sklice)	Sklice 0.5% Lotion	NF	\$350.26	
Lindane Shampoo	1% shampoo	NF	--	
Malathion (Ovide)	0.5% Lotion	ST,QL	\$177.29	Step therapy to failure of at least 2 (two) documented treatment courses of permethrin 1% in the last 30 day; Restricted to 60 ml per 90 days; CDC recommends against use in < 2 years of age, despite FDA labeling which states for use in patients ≥ 6.
Permethrin (Nix)	1% Lotion	--	\$7.08	
	Nix 1% Lotion	--	\$9.76	
Pyrethrins and piperonyl butoxide (RID)	0.33%/4% Shampoo	--	\$5.13	
Spinosad (Natroba)	0.9% Suspension	ST,PA	\$173.11	Step therapy to failure of at least 2 (two) documented treatment courses of permethrin 1% in the last 30 days.
<b>SCABBIES TREATMENT (Scabicide):</b>				
Crotamiton (Eurax)	Eurax 10% Cream/Lotion	ST,PA	\$496.925	Step therapy to failure of at least 2 (two) documented treatment courses of permethrin 5 % cream in the last 30 days.
Lindane Shampoo	1% shampoo	NF	--	
Permethrin (Elimite)	5% Cream	--	\$73.70	
Ivermectin (Stromectol)	3 mg Tablets	NF	\$24.40	
<b>Antiprotozoal</b>				
Alinia Oral	100 mg/ 5 ml Ssuspension	NF	\$527.59	
<b>Anthelmintic</b>				

Albendazole (Albenza)	200 mg Tablets	QL	\$483.16	Limited to 2 tablets per 180 days; *Submit PA for larger quantity
	Albenza 200 mg Tablets	QL	\$609.55	
Ivermectin (Stromectol)	3 mg Tablets	NF	\$24.40	
Mebendazole (Emverm)	100 mg Chewable Tablets	NF	--	
Praziquantel (Biltricide)	600 mg Tablets	NF	\$55.80	
	Biltricide 600 mg Tablets	NF	--	
Pyrantel Pamoate oral suspension (Reese Pinworm, Pin-X)	Pin-X 50 mg/ml	--	\$7.03	
	Reese Pinworm 50 mg/ml	--	\$5.96	

PA = Prior Authorization, ST = Step Therapy, NF = Non-Formulary, QT = Quantity Limit

## **EVALUATION CRITERIA FOR APPROVAL/EXCEPTION CONSIDERATION**

Below are the coverage criteria and required information for each agent. These coverage criteria have been reviewed approved by the HPSJ Pharmacy & Therapeutics (P&T) Advisory Committee. For conditions not covered under this Coverage Policy, HPSJ will make the determination based on Medical Necessity as described in HPSJ Medical Review Guidelines (UM06).

**Pediculocide Agent: Permethrin 1%, Pyrethrins/piperonyl butoxide, Malathion, Spinosad, Benzyl Alcohol, Lindane, Ivermectin, Benzy Benzoate**

### ***Permethrin 1% (NIX), Pyrethrins/piperonyl butoxide (RID)***

- Coverage Criteria:** None
- Limits:** None
- Required Information for Approval:** N/A
- Other Notes:** Retreatment on day 9 is recommended if live lice are seen. There is no evidence that using the higher strength (5%) permethrin has any effect on resistance or efficacy.

### ***Malathion (Ovide)***

- Coverage Criteria:** Ovide is step therapy to failure of at least 2 (two) documented treatment courses of permethrin 1% in the last 30 days.
- Limits:** 60 mL per 90 days
- Required Information for Approval:** Pharmacy fill history of at least 2 treatment courses of permethrin 1%
- Other Notes:** It is only approved for patients older than 6 due to theoretical risk of respiratory depression. CDC recommends against use in children < 2 years of age. Due to partial ovicidal effect, a second treatment is recommended if live lice still are present 7–9 days after treatment.<sup>1</sup>

### ***Spinosad (Natroba)***

- Coverage Criteria:** Step therapy to failure of at least 2 (two) documented treatment courses of permethrin 1% in the last 30 day
- Limits:** None
- Required Information for Approval:** Chart notes indicating treatment failure and pharmacy fill history of permethrin 1% in the last 30 day.
- Other Notes:** Pediculicidal and ovicidal. Retreatment is usually not needed. Nit removal is not needed.<sup>1</sup>

### ***Benzyl Alcohol (Ulesfia)***

- Coverage Criteria:** Reserved for treatment failure of Spinosad (Natroba) AND Malathion (Ovide) in the last 30 days **Limits:** None
- Required Information for Approval:** Chart notes and pharmacy fill history of Spinosad AND Malathion (Ovide) in the last 30 days

- Other Notes:** Coverage criteria for Spinodad (Natroba) and Malathion are listed above. Ulesfia is not ovicidal. Second treatment is needed 7 days after the treatment to kill newly hatched lice. Approved for use in age 6 months and older. Safety of use in age more than 60 has not been established.
- Non-Formulary:** Lindane Shampoo (retreatment is not recommended<sup>1</sup>), Ivermectin (Sklice), Benzy Benzoate

**Scabicial Agent: *Crotamiton, Lindane, Permethrin 5%, Ivermectin***

***Crotamiton (Eurax)***

- Coverage Criteria:** Step therapy to failure of at least 2 (two) documented treatment courses of permethrin 5% cream in the last 30 days.
- Limits:** None
- Required Information for Approval:** Chart notes and pharmacy fill history of at least 2 treatment courses of permethrin 5% cream in the last 30 days.

***Permethrin 5% (Elimite)***

- Coverage Criteria:** None
- Limits:** None
- Required Information for Approval:** N/A
- Non-Formulary:** Lindane Shampoo, Ivermectin (Stromectol) tablets

**Anthelmintic Treatment; *Albendazole (Albenza), Ivermectin (Stromectol), Nitazoxanide (Alinia), Praziquantel (Biltricide), Pyrantel Pamoate (Pin-x, Reese Pinworm)***

***Pyrantel Pamoate oral suspension (Pin-x, Reese Pinworm)***

- Coverage Criteria:** None
- Limits:** None
- Required Information for Approval:** N/A
- Other Notes:** None

***Albendazole (Albenza)***

- Coverage Criteria:** Albendazole is limited to 2 tablets per 180 days without prior authorization
- Limits:** 2 tablets per 180 days
- Required Information for Approval:** N/A
- Other Notes:** For quantities greater than 2 tablets, please submit a prior authorization request. Please include chart notes with a diagnosis, duration of treatment, and dosing frequency.
- Non-Formulary:** Ivermectin (Stromectol), Praziquantel (Biltricide), Mebendazole (Emverm), Nitazoxanide (Alinia)

**Clinical Justification:**

Currently Pyrethrins and permethrin containing head lice medications are available over the counter which are effective and safe when used as directed. CDC recommends retreatment in 9 to 10 days. If crawling lice are seen after a full course of treatment, a prescriber should be contacted.

Due to concerns of overuse, misuse, or accidentally swallowing Lindane which can be toxic to brain and other parts of nervous system, the American Academy of Pediatrics (AAP) no longer recommends it as a pediculocide. Although lindane shampoo 1% is approved by the FDA for the treatment of head lice, it is not recommended as a first-line treatment. Lindane is not recommended for use in premature infants, persons with HIV, a seizure disorder, women who are pregnant or breast-feeding, persons with skin irritations and patients whose weight is less than 110 lbs. Retreatment should be avoided.

Benzy benzoate has scabicial and pediculicidal activities, it is not considered as treatment of choice of alternative choice for scabies<sup>1</sup>. Although the manufacture recommends Benzy benzoate for treatment of head lice and pubic lice, CDC does not include Benzy benzoate as one of the options for lice treatment. Therefore it is not on HPSJ formulary.

Although Ivermectin has been used as off label use for lice and scabies treatment, due to various systemic concerns and lack of strong evidence, it is non-formulary. As more evidence-based effectiveness becomes available and with each specific cases, Ivermectin will be reviewed and considered on medical necessity basis.

***Anthelmintic Drugs:***

Helminths are multicellular parasites of various classes and orders. Some example infections include: Pinworm (*Enterobiasis*), Whipworm (*Tricuriasis*), and Hookworm (*Necator americanus*). Pyrantel Pamoate is usually the drug of choice for these infections, is widely available, and is over-the-counter. Pyrantel Pamoate is a first line option.

Albendazole is a broad-spectrum anthelmintic that can be used for a variety of infections. In many cases, infections requiring treatment with albendazole can be treated in 1 or 2 doses. For infections that require more than 1-2 doses, please submit a prior authorization for review.

(Some drugs for helminth infections are available as limited distribution drugs only through the CDC. Please check <http://www.cdc.gov/laboratory/drugservice/> for a full list of covered drugs.)

## ☒ REFERENCES

1. CDC Lice Treatment Guidelines. Available at: <http://www.cdc.gov/parasites/lice/head/treatment.html>
2. Pourhasan A, Goldust M, Rezaee E. *Treatment of scabies, permethrin 5% cream vs. crotamiton 10% cream*. Ann Parasitol. 2013; 59(3):143-7.
3. Strong M, Johnstone P. *Interventions for treating scabies*. Cochrane Database Syst Rev. 2007 Jul 18 ;(3):CD000320.
4. Taplin D, Meinking TL, Chen JA, Sanchez R. *Comparison of crotamiton 10% cream (Eurax) and permethrin 5% cream (Elimite) for the treatment of scabies in children*. Pediatr Dermatol. 1990 Mar;7(1):67-73.
5. CDC Scabies Treatment. Available at: [http://www.cdc.gov/parasites/health\\_professionals/med.html](http://www.cdc.gov/parasites/health_professionals/med.html)

## ☒ REVIEW & EDIT HISTORY

Document Changes	Reference	Date	P&T Chairman
Creation of Policy	Formulary Realignment PT 5-21-13.xlsx	5/2013	Allen Shek PharmD BCPS
Update to Policy	HPSJ Coverage Policy – Infectious Disease – Parasitic Disorders 2015-05.docx	5/2015	Jonathan Szkotak, PharmD, BCPCS
Update to Policy	HPSJ Coverage Policy – Infectious Disease – Parasitic Disorders 2016-12.docx	12/2016	Johnathan Yeh, PharmD
Update to Policy	HPSJ Coverage Policy – Infectious Disease – Parasitic Disorders 2017-12.docx	12/2017	Johnathan Yeh, PharmD
Update to Policy	HPSJ Coverage Policy – Infectious Disease – Parasitic Disorders 2019-2.docx	2/2019	Matthew Garrett, PharmD

Note: All changes are approved by the HPSJ P&T Committee before incorporation into the utilization policy

## Appendix 1: Lice Treatment Chart

Pharmacological Treatment Options for Head Lice							
Drug	Brand Name(s)	Dosing	Form Status	Ages	Notes	Efficacy	Adverse Effects
<b>Permethrin</b>	NIX	Topically x 1 dose, retreat on day 9	F	≥ 2 months	Kills live lice only, leaves residue on hair	43-100%	Stinging (10%) Itching (7%) Rash (<2%)
<b>Pyrethrins and piperonyl butoxide</b>	RID	Topically x 1 dose, retreat on day 9	F	≥ 2 years	Kills live lice only	62-100%	Itching (35%)
<b>Malathion</b>	Ovide	Topically x 1 dose, retreat on day 7-9 (if necessary)	F, ST	≥ 6 years	Kills lice and some eggs, flammable	90%	Itching* Rash*
<b>Benzyl Alcohol</b>	Ulesfia	Topically x 1 dose, retreat on day 7	F, ST	≥ 6 months	Kills live lice only, resistance not possible.	76%	Itching (12%) Redness (10%) Numbness (2%)
<b>Ivermectin lotion</b>	Sklice	Topically x 1 dose	PA	≥ 6 months	Kills live lice and nymphs	71-76%	Itching (2.8%) Dry skin* Burning*
<b>Spinosad</b>	Natroba	Topically x 1 dose	PA	≥ 4 years	Kills lice and eggs	85%	Irritation (1%) Redness (3%)

Adapted from "Class Review of Therapies for Pediculus Capitis (Head Lice)"